Citation:

Frisch S, Zittermann A, Berthold HK, Götting C, Kuhn J, Kleesiek K, Stehle P, Körtke H. A randomized controlled trial on the efficacy of carbohydrate-reduced or fat-reduced diets in patients attending a telemedically guided weight loss program. *Cardiovasc Diabetol.* 2009 Jul 18;8:36.

PubMed ID: 19615091

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate whether or not a carbohydrate-restricted diet telemedically guided weight loss program during 12 months results in a more pronounced weight loss and influences metabolic risk markers more beneficially than a fat-restricted diet.

Inclusion Criteria:

- Ages 18 to 70 years old
- BMI >27 kg/m^2

Exclusion Criteria:

- Subjects with any symptoms of CVD
- Subjects with ischemia after an exercise electrocardiogram and stress echocardiography when appropriate
- Subjects with cholelithiasis, urolithiasis, insulin dependent diabetes mellitus, pacemaker implantation
- Pregnancy, lactation and vegetarianism
- Participation in another weight loss program and medical treatment for weight reduction

Description of Study Protocol:

Recruitment : The participants were recruited in November 2005 by advertisements in local newspapers and by providing information sheets at different local health insurance offices.

Design: Randomized Controlled Trial

Blinding used (if applicable): not reported

Intervention (if applicable):

- Low-carbohydrate diet (less than 40% of energy from carbohydrate, more than 35% of energy from fat, 25% energy from protein)
- Low-fat diet (less than 30% of energy from fat, more than 55% of energy from carbohydrate, 15% of energy from protein)

Statistical Analysis:

- When the variables were not normally distributed, these data were normalized using logarithm transformation
- Unpaired T-test was used to compare continuous values of the study groups at baseline and between groups to specify time points at 6 and 12 months with significant differences for anthropometric, clinical and biochemical parameters. Paired T-test for differences within groups.
- Chi Square test was used for comparative evolution of categorical variables
- Two-factor analysis of covariance was used to compare between the two groups with its respective baseline value and with fat-free mass and sex distribution as covariates.
- Missing data were replaced with baseline data in the intention-to-treat analysis.
- P value <0.05 was considered statistically significant.

Data Collection Summary:

Timing of Measurements:

- The study was conducted between December 2005 and November 2006.
- During the first six months weight, nutrition education and dietary counseling by phone were weekly.
- At baseline, after six months, and after twelve months, anthropometric, body composition, and biochemical parameters were measured.
- Energy and nutrient intake were assessed at baseline, 1, 3, 6, and 12 months.

Dependent Variables

- BMI
- Height
- Weight - all participants received an electronic scale with added Bluetooth technology, therefore, the actual body weight data was sent weekly to the Institute.
- Fat mass
- Fat free
- Waist circumference
- Triglycerides
- Total cholesterol
- HDL-cholesterol
- LDL-cholesterol
- Glucose
- HbA1c
- Proinsulin
- Adiponectin
- Blood pressure

Independent Variables

- Low-carbohydrate diet (LOGI group) vs low-fat diet (DGE group); all participants were advised to reduce their daily energy intake by at least 500 kcal. The weight reduction program consisted of nutrition education and dietary counseling by phone with a nutritionist.
- Energy intake and nutrient intake were assessed using a 3-day validated food record
- Daily physical activity was measured using a standardized, validated questionnaire

Control Variables

- Antihypertensive drugs
- Lipid-lowering drugs
- Antidiabetic drugs

Description of Actual Data Sample:

Initial N: 200 (124M; 76F). 76 subjects refused to participate after a first phone screen; 16 people did not meet the inclusion criteria; 6 were excluded at the baseline investigation.

Attrition (final N): 165

Dropouts (N): non-compliance with the weight reduction program (23); personal reasons (7); diagnosis of Guillain-Barré Syndrome (1); diagnosis of a malignancy requiring chemo preventive therapy (1); pregnancy (3)

Age: mean age 47±10.5 years

Ethnicity: not mentioned

Other relevant demographics: The sample had sixty-two percent of men. Medication used was similar between groups at baseline and did not chance during the study period. Forty-three percent of the subjects were smokers. Half of the subjects had Metabolic Syndrome with fifty-four percent belonging to the low-fat group and forty-five percent to the low-carbohydrate group.

Anthropometrics: BMI, weight, waist circumference and fat mass were well matched between the two groups. However, fat-free mass was higher in the low-carbohydrate group.

Location: Bed Oeynhausen, Germany

Summary of Results:

Key Findings

- Energy intake decreased by approximately 400kcal/day during the first six months compared to baseline in low-carbohydrate diet group (1742±624 vs 2140±696 kcal) and low-fat diet group (1783±597 vs 2192±668 kcal, respectively). However, after twelve months, mean energy intake has slightly increased again in the low-carbohydrate diet group with 1866±710 kcal and low-fat group with 1854±624 kcal but remained below baseline values
- Both diets resulted in similar weight loss. At the end of the study weight loss was 5.8±6.1kg in the low-carbohydrate diet group and 4.3±5.1kg in the low-fat diet group; P=0.065. Changes in the BMI was not statistically different during the study in both groups.

Approximately 76% of weight reduction observed in both groups was due to a loss of fat mass

- Changes in fat mass and fat free mass were not statistically different during the study in both groups
- Waist circumference decreased in both study groups, however, the changes in the decrease was more pronounced in the low-carbohydrate diet group compared with low-fat diet group after twelve months; -6.9±6.1 vs -4.7±8.9; P=0.037, even when adjustments were made for fat-free mass, and sex distribution.

Changes in metabolic and cardiovascular risk factors (intention-to-treat-analysis)

Variables	*DGE group	**LOGI group	P value
Triglyceride (mmol/L) 6 months	-0.03±0.55	-0.18±0.40	0.005
12 months	-0.04±0.50	-0.10±0.47	0.164
Total cholesterol(mmol/L) 6 months	-0.07±0.50	-0.07±0.56	0.926
12 months	0.13±0.61	0.03±0.75	0.259
LDL-cholesterol (mmol/L) 6 months	-0.03±0.51	-0.03±0.50	0.921
12 months	0.06±0.59	0.02±0.65	0.564
HDL-cholesterol(mmol/L) 6 months	-0.09±0.19	-0.02±0.20	0.005
12 months	-0.03±0.17	-0.02±0.21	0.668
Systolic pressure(mmHg) 6 months	-4±15	-6±16	0.102
12 months	-1±15	-5±14	0.007
Diastolic pressure (mmHg) 6 months	-3±9	-3±8	0.884
12 months	-2±8	-3±9	0.440

*Low-fat diet group; **Low-carbohydrate diet group

Other Findings

- The DGE group did not achieve the target for carbohydrate intake (>55%). The carbohydrate intake range was between 49% to 50% while, LOGI group was approximately between 38% to 44%.

- Changes in parameters of glucose metabolism were similar between groups

Author Conclusion:

Despite favorable effects of both diets on weight loss, the carbohydrate-reduced diet was more beneficial with respect to cardiovascular risk factors compared to the fat-reduced diet. Nevertheless, compliance with a weight loss program appears to be even more a important factor for success in prevention and treatment of obesity than the composition of the diet.

Reviewer Comments:

Groups were significantly different in terms of gender and fat free mass. The carbohydrate intake in the low-fat-high carbohydrate diet was normal which compromises the comparisons between high versus low carbohydrate intake, therefore, the outcomes as well. Most of the participants in the study were male therefore the results should be translated carefully for the general population.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes

2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	No
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	No
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	???
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes